IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FIRST QUALITY TISSUE, LLC, Plaintiff, v. IRVING CONSUMER PRODUCTS LIMITED and IRVING CONSUMER PRODUCTS, INC., Defendants.	)	C.A. No. 19-428 (RGA)

DEFENDANTS IRVING CONSUMER PRODUCTS LTD.'S AND IRVING CONSUMER PRODUCTS, INC.'S OPENING BRIEF IN SUPPORT OF THEIR RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW UNDER FED. R. CIV. P. 50(b)

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
rsmith@morrisnichols.com

Attorneys for Defendants

OF COUNSEL:

Matthew J. Moore
Maximilian A. Grant
Inge A. Osman
Rebecca L. Rabenstein
David A. Zucker
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004-1304
(202) 637-2200

Charles H. Sanders
David W. Rowe
Paul Weinand
LATHAM & WATKINS LLP
200 Clarendon Street
Boston, MA 02116
(617) 948-6000

Dale Chang
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
(312) 876-7700

John G. Day (#5207)
Andrew C. Mayo (#2403)
ASHBY & GEDDES
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19801
(302) 654-1888
jday@ashbygeddes.com
amayo@ashbygeddes.com

Jeffrey G. Homrig
LATHAM & WATKINS LLP
140 Scott Drive
Menlo Park, CA 94025
(650) 328-4600

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I. NATURE AND STAGE OF PROCEEDINGS

Before trial, the Court denied defendants Irving Consumer Products Limited's and Irving Consumer Products, Inc.'s (collectively, "Irving's") motion for summary judgment of invalidity under 35 U.S.C. § 112. D.I. 312 (Memorandum Opinion). Based on plaintiff First Quality Tissue, LLC's ("FQ's") representations about its experts' expected trial testimony, the Court found "a genuine dispute of material fact as to whether the Asserted Patents' written description is sufficient," and "disputed factual issue[s]" about whether the asserted claims are indefinite. *Id.* at 9, 18. These issues were submitted to the jury, which returned a verdict of no invalidity on lack of written description and indefiniteness. D.I. 387 (Verdict).

The evidence presented at trial, however, compels a finding that the asserted claims of U.S. Patent Nos. 9,506,203 (PTX-001), 9,580,872 (PTX-003), and 9,752,853 (PTX-005) lack sufficient written description and are indefinite. Thus, Irving respectfully requests a ruling that asserted claims 1 and 3 of the '203 patent, claims 1 and 4 of the '872 patent, and claims 4, 12, and 13 of the '853 patent are invalid as a matter of law for lack of written description and indefiniteness.

II. SUMMARY OF THE ARGUMENT

1. The asserted claims lack written description support as a matter of law for two reasons. First, the patents fail to "reasonably convey to those skilled in the art that the inventor[s] had possession" of the full scope of the claimed numerical ranges. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Each asserted claim recites "Average Peak to Valley Waviness [Wc] of 140 microns or less," but unrebutted trial testimony establishes that the patents disclose only a single example within that range, having a Wc of 123. Tr. 823:17-824:3 (Keller direct). As a matter of law, disclosure of a single species at the high end of a broad range cannot support a broad genus claim. *Ariad*, 598 F.3d at 1349-51. Notably, to

avoid summary judgment, FQ had relied on statements from its expert, Dr. Runge, that "the claimed Wc and Pa ranges have an inherent lower limit" other than zero, and a POSA would know how to create tissue throughout that range. D.I. 312 at 19. At trial, however, FQ failed to adduce any such testimony, or any other testimony that could support a finding of adequate written description. There is therefore no substantial evidence to support the jury's verdict of no invalidity for lack of written description.

2. Second, the asserted claims lack written description support as a matter of law because the four corners of the patent undisputedly contain *no examples* of surface properties calculated in the manner required by the Court's claim construction. The Court ruled that "the claims require Wc and Pa values to be obtained by averaging 200 scans from ten samples." D.I. 275 (Supplemental Claim Construction Order). Yet FQ's inventor repeatedly testified that the Wc and Pa values disclosed in the asserted patents were based on averaging twenty scans from just *one* sample, as expressly stated in the asserted patents. *See, e.g.*, Tr. 177:9-11 (Sealey cross); PTX-001.11, 9:54-56 ("The calculated values of Pa and Wc *for all twenty scans* were averaged to obtain Pa and Wc values *for each tissue sample*.").[1] Expert testimony confirmed this. Tr. 824:16-19 (Keller direct). FQ identified no disclosure of any Wc value for ten samples, as required by the Court's construction, because there is none. The asserted patents thus fail to meet a fundamental written description requirement as a matter of law: "[w]hat is claimed by the patent applica[nt] must be the same as what is disclosed in the specification." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002).

[1] Because the asserted patents share a specification, citations are provided only to the '203 patent. All emphases added and internal quotation marks omitted unless otherwise noted.

3. The asserted claims are invalid for indefiniteness as a matter of law because unrebutted evidence establishes that: (1) there are multiple methodologies for measuring Wc; (2) those methodologies lead to materially different results; and (3) the asserted patents fail to provide guidance as to which methodology to use. *See Dow Chem. Co. v. Nova Chems Corp. (Can.)*, 803 F.3d 620, 634 (Fed. Cir. 2015). Unrebutted test results show that a person of ordinary skill in the art's (POSA's) choice of how to test with respect to embossments (*e.g.*, by choosing different distances between scan lines) materially affects the Wc values. *E.g.*, Tr. 821:3-13; 822:21-823:10 (Keller direct). FQ's experts conceded that they had not offered relevant opinions or performed any testing to contest this. *See* Tr. 619:21-620:6 (Runge cross); Tr. 495:20-496:2 (Brown cross). The trial testimony confirmed that the patents, however, do not explain how to account for embossments or how far apart to space the scan lines. Tr. 482:22-483:3 (Brown direct) ("the patent is silent on whether or not you test over embossments."); Tr. 820:18-25, 821:14-21 (Keller direct). The patents are thus indefinite as a matter of law. *See Dow*, 803 F.3d at 634.

III. STATEMENT OF FACTS

The asserted patents each state that "the roughness of tissue can be characterized using two values, Pa (Average Primary Amplitude) and Wc (Average Peak to Valley Waviness)." PTX-001 ('203 patent) at 9:16-18. Each asserted claim recites a "through air dried tissue . . . comprising an outer surface having an Average Peak to Valley Waviness of 140 microns or less." *Id.* cls. 1 and 3; PTX-003 ('872 patent) cls. 1 and 4; PTX-005 ('853 patent) cls. 4, 12, and 13.

At trial, Irving adduced evidence that every asserted claim is invalid for lack of written description support and indefiniteness, mainly through its expert Dr. Keller. In response, FQ's expert Dr. Runge provided only a vague, conclusory statement that "there was a lot of details in this patent." Tr. 1053:10-16 (Runge rebuttal direct). In fact, Dr. Runge, along with FQ's other

expert, Dr. Brown, and FQ's lead inventor, Dr. Sealey, provided testimony that supports invalidity. The relevant testimony is detailed below.

IV. LEGAL STANDARDS

Judgment as a matter of law is appropriate "where a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have had a legally sufficient evidentiary basis to find for the party on that issue." *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1153-54 (Fed. Cir. 2019), *cert. denied* 141 S. Ct. 1234 (2021) (applying Third Circuit law). To prevail, a movant "'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied by the jury's verdict cannot in law be supported by those findings.'" *Ateliers de la Haute-Garonne v. Broetje Automation-USA Inc.*, 85 F. Supp. 3d 768, 775 (D. Del. 2015) (quoting *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998)).

The written description requirement demands that the specification "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad*, 598 F.3d at 1351. "In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* "The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, [the specification] itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

The definiteness requirement "require[s] that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910

(2014). Under *Nautilus*, a claim that requires a measurement is indefinite where "multiple known approaches exist," leading to different results, and a person of ordinary skill (POSA) would not "know which approach to select." *Dow*, 803 F.3d at 630; *see also Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1344-45 (Fed. Cir. 2015) (claim indefinite where it "can be ascertained by any of three possible measures" and "specification never defines" which one to use). In other words, "where the claim requires a specific measurement or calculation, more than one measurement method may be used, and no guidance has been provided," it is indefinite. *Pac. Coast Bldg. Prods., Inc. v. CertainTeed Gypsum, Inc.*, 816 F. App'x 454, 458 (Fed. Cir. 2020).

V. ARGUMENT

Judgment of invalidity for lack of written description and indefiniteness as a matter of law is warranted for three independent reasons. ***First***, the asserted claims lack written description because every claim requires Wc "of 140 microns or less," but unrebutted evidence shows that the specification discloses only a single example at the upper end of that range, which as a matter of law cannot establish that the inventors possessed the entire claimed range. ***Second***, the asserted claims lack written description support because the patents undisputedly contain *no disclosure* of Wc values based on testing ten samples, as the Court's claim construction requires. ***Third***, the asserted claims are indefinite because unrebutted evidence establishes that there are multiple ways to measure Wc that yield materially different results, and the patents undisputedly do not clarify which method to use.

A. The Claimed Wc Range Of "140 Microns Or Less" Lacks Written Description Support As A Matter Of Law

The jury's verdict of no invalidity for lack of written description is not supported by substantial evidence. The single relevant Wc value disclosed in the patents is legally insufficient to support the claimed breadth of Wc values. When claims cover a broad genus, "the

specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus." *Ariad*, 598 F.3d at 1349. Here, every asserted claim recites a broad genus of tissue having outer surfaces with Wc of "140 microns or less," but the specification fails to disclose "species sufficient to support" this claimed range. *Id.* As in *Ariad*, the asserted claims here thus lack written description as a matter of law because the single example disclosed in the specification cannot support the broad claimed range of Wc. *Id*. at 1349-51.

At trial, unrebutted evidence confirmed that the asserted patents disclose just one example of a tissue having Wc within the claimed range. Tr. 823:17-21 (Keller direct). The patents disclose that this example, "Example 5" in the specification, has a Wc (123.41 microns) at the upper end of the claimed range. *Id.*; PTX-001.11, 10:30. Dr. Keller explained, "[t]hat is the only example" in the patents, and it "falls very near the top of the claim limit [of 140]." Tr. 823:22-824:3. There is no contrary evidence in the trial record.

FQ asked its expert Dr. Runge just two questions about the patents' written description. In responding to both, he vaguely stated that the asserted patents provide "a lot of detail[s]," but failed to identify any of those details or how they might provide written description support. Tr. 1022:16-1023:1; 1053:10-16 (Runge rebuttal direct). Such conclusory testimony, "not supported by any evidence at all," cannot show adequate written description. *Anascape, Ltd. v. Nintendo of Am. Inc.*, 601 F.3d 1333, 1339 (Fed. Cir. 2010); *see also Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1363-64 (Fed. Cir. 2011) ("no reasonable jury could conclude that there is sufficient written description support" for examples about which the specification "contains virtually no information").

Because the record evidence confirms that the specification discloses only a single example tissue having a Wc at the upper end of the claimed range, each asserted claim lacks written description support as a matter of law. When patents disclose only a single example toward one end of a claimed range, as here, that is a telltale sign of invalidity for lack of written description as a matter of law. *See Lipocine Inc. v. Clarus Therapeutics, Inc.*, 541 F. Supp. 3d 435, 458-59 (D. Del. 2021) (Bryson, J., sitting by designation) (claims invalid for lack of written description as a matter of law because claimed range not supported by disclosures "at the low end," or "near the bottom" of the range); *see also AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014) ("analogizing the genus to a plot of land, if the disclosed species only abide in a corner of the genus, one has not described the genus sufficiently to show that the inventor invented, or had possession of, the genus. He only described a portion of it."); *Eiselstein v. Frank*, 52 F.3d 1035, 1040 (Fed. Cir. 1995) (disclosure of half the claimed range—"45-55%"—insufficient to support claims to "about 50 to about 60%").

The Federal Circuit has repeatedly affirmed these principles in reviewing JMOL decisions addressing written description. In *Idenix*, the court reversed the district court's denial of JMOL, holding the asserted patent invalid for lack of written description, because it failed to demonstrate "possession of those [examples] that fall within the boundaries of the claim . . . but are not encompassed by the explicit formulas or examples provided in the specification." *Idenix*, 941 F.3d at 1163. The record here compels the same result. There is no evidence that the asserted patents reflect possession of any tissue with a Wc below, e.g., 100 microns. Tr. 823:17-824:3 (Keller direct). Thus, there is no written description for ***over 70%*** of the claimed range. *Idenix*, 941 F.3d at 1163; *see also Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1341 (Fed.

Cir. 2021) (reversing denial of JMOL for lack of written description, and holding patent invalid, where specification provided only two examples within a broad claimed genus).

The disparity between FQ's trial testimony and its prior arguments to this Court further reinforces the lack of substantial evidence for the jury's verdict on written description. In denying Irving's summary judgment motion, the Court held that "a factfinder could reasonably conclude from Dr. Runge's testimony that a POSA would understand the inventors [possessed the full range of the claimed invention]." D.I. 312 at 20. The Court relied on two aspects of Dr. Runge's anticipated testimony: (1) that "[n]o actual real world tissue surface has a Pa or Wc . . . of zero microns," and therefore the claimed ranges "have a practical lower limit" other than zero; and (2) that the specification "explain[s] how to adjust various aspects of the tissue making process to achieve . . . surface profiles less than the claimed upper limit(s)." *Id.* 19-20. At trial, however, Dr. Runge ***did not offer testimony on either point***. FQ adduced no evidence at trial that the claims have a practical lower limit other than zero. Nor did FQ adduce any evidence that the specification enables a POSA to adjust aspects of the tissue making process to achieve tissues with other Wc values less than Example 5's 123 microns. Thus, the "genuine dispute of material fact" that FQ represented its expert would raise through testimony at trial does not exist in the trial record. *Id.* at 18. FQ's failure to offer substantial evidence that could support the jury's verdict compels JMOL that the claims are invalid for lack of written description.

B. There Is No Written Description Support For Any Wc Value Calculated Under The Court's Claim Construction

The asserted claims are invalid for lack of written description for another, independent reason: the specification undisputedly provides *no disclosure* of any Wc value calculated in accordance with the Court's claim construction.

The Court ruled "that the claims require Wc and Pa values to be obtained by averaging 200 scans from ten samples." D.I. 275 at 5. It is undisputed, however, that the patents do not disclose any Wc or Pa values calculated in this way. The trial record establishes that, as the specification expressly states, the Wc and Pa values for each tissue sample were calculated by averaging "twenty scans" from one sample—not 200 scans from ten samples: "The calculated values of Pa and Wc *for all twenty scans* were averaged to obtain Pa and Wc values *for each tissue sample*." PTX-001.11, 9:54-56.

Dr. Sealey, the only inventor to testify at trial, admitted that all of the Wc and Pa values disclosed in the asserted patents instead "were measured based on 20 scans from one sample." Tr. 177:9-11 (Sealey cross). He repeatedly and unambiguously testified that Tables 2 and 3 of the asserted patents—the only portions of the specification that recite Wc or Pa values—were created by averaging 20 scans from one tissue sample:

> Q. And the Pa and Wc values in Tables 2 [and 3], they were ***measured based on 20 scans from one sample***; correct?
>
> A. ***Correct***.

Tr. 177:9-11 (Sealey cross).

> Q. Okay. So you ***only took 20 scans to measure the Pas and Wcs*** in Table 2; correct?
>
> A. ***Right. Correct***.

Tr. 177:23-25 (Sealey cross).

> Q. And so if we look at – for example, let's look at this Charmin purchase in June 2012, Charmin soft. The Charmin soft that was purchased in June 2012, ***the data disclosed here in Tables 2 and 3 was only based on 20 scans from one sample***; correct?
>
> A. ***Correct***.

Tr. 177:12-17 (Sealey cross); *see also* Tr. 173:24-174:1 (confirming same).

Dr. Keller testified that a POSA reading the specification would understand that its Wc values were generated from "20" scans for an "individual sample," in contrast to the "200 scans" the Court's construction requires. Tr. 824:6-19 (Keller direct). No FQ witness disputed this testimony. Nor did any FQ witness identify any disclosure of Wc values calculated by "averaging 200 scans from ten samples." D.I. 275 at 5.

The trial record thus confirms that the patents disclose no tissue having Wc within the claimed ranges "obtained by averaging 200 scans from ten samples," and accordingly the asserted claims lack written description as a matter of law. D.I. 275 at 5. The inventors did not have "possession" of any Wc value calculated in the manner the claims require, let alone possession of the entire claimed range.[2] *Ariad*, 598 F.3d at 1351; *see also Neology, Inc. v. Int'l Trade Comm'n*, 767 F. App'x 937, 943 (Fed. Cir. 2019) (affirming that the lower court "could reasonably rely . . . on the inventor's own testimony" that highlighted the lack of written description). Where, as here, "the patent specification fails to disclose" an element of the claimed invention, JMOL is warranted because "no reasonable jury could conclude that the [specification] provides adequate written description." *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1350-51 (Fed. Cir. 2013) (affirming grant of JMOL of no written description). As a result, judgment as a matter of law in Irving's favor is warranted, even without reliance on Irving's extrinsic evidence that the Court considered "irrelevant" and excluded Irving from presenting at trial.[3] Tr. 564:14-569:24.

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[2] For brevity, Irving focuses its argument on Wc. The asserted claims are also invalid because the patents do not disclose "Waviness Uniformity of 27 microns or less," "Average Primary Amplitude of 50 microns or less," and "Amplitude Uniformity of 8 microns or less" obtained from 200 scans on ten samples.

[3] The Court's evidentiary ruling tracked its reasoning in its summary judgment decision that "[l]ack of written description cannot be proven by the sort of extrinsic evidence Irving offers."

The patents do not disclose what the Wc of the Example 5 tissue (or any other tissue) would have been, if it had been calculated by averaging 200 scans from 10 samples. To be clear, there is ***no record evidence*** to support the proposition that a POSA could, from the disclosed Wc value obtained for 1 sample, extrapolate to obtain Wc values for 10 samples. And even if there were such evidence, it would not cure the lack of written description. The question of written description "is not whether one of ordinary skill in the art presented with the [specification] would have been enabled to take those final steps, but whether the [specification] discloses the [invention] to him, ***specifically***, as something [FQ] actually invented." *Novozymes*, 723 F.3d at 1250. The undisputed trial record establishes that the specification does not specifically disclose a single Wc within the claimed range calculated using 200 scans from 10 samples.

C. The Asserted Claims Are Indefinite As A Matter Of Law

The asserted claims are indefinite as a matter of law because unrebutted evidence establishes that (1) there are multiple methodologies to measure the claim limitation "Average Peak to Valley Waviness" (Wc); (2) those methodologies lead to materially different results; and (3) the asserted patents fail to provide guidance as to which methodology to use. *Dow*, 803 F.3d at 634.

1. There Are Undisputedly Multiple Methodologies To Measure Wc

The asserted patents, and the Court's claim constructions, require scanning each sample of tissue with a Mahr profilometer "ten [times] in the forwards direction and ten [times] in the backwards direction." PTX-001 ('203 patent) at 9:39-43. There are multiple methodologies a

D.I. 312 at 20. Irving objects to these rulings again to ensure that its right to appeal is preserved. *See Frank C. Pollara Grp., LLC v. Ocean View Inv. Holding, LLC*, 784 F.3d 177, 187 (3d Cir. 2015) ("if an earlier dispositive argument is not renewed through motions for [JMOL], the litigant propounding the argument may not seek appellate review of a decision rejecting it . . .").

POSA can use to perform those ten forward and ten backwards scan lines. In particular, assuming a POSA will scan over different lines, a POSA can choose how far apart to space the scan lines.

Irving presented unrebutted evidence that a POSA can choose from among "different spacings" between scan lines—*e.g.*, "1-millimeter, 2-millimeter and 5-millimeter spacings"—because the patents do not tell a POSA how far apart to space the scans or how to account for embossing. Tr. 820:23-821:21 (Keller direct). FQ did not rebut this evidence. FQ introduced no evidence that a POSA would know to pick a particular spacing. Indeed, FQ could not have done so because its own expert did not actually use the spacing he had said he had used. Dr. Runge said that he spaced his ten scans "2 millimeters apart," for a total of 20 mm (or 2 cm), but conceded on cross examination that the scans were actually only about 1 mm apart, for a total of 10 mm (or 1 cm), and would have intersected more embossing if he had actually scanned 20 mm (or 2 cm). Tr. 629:23-630:19, 632:17-634:6 (Runge cross).

2. Unrebutted Evidence Shows That Different Wc Methodologies Yield Materially Different Results

Dr. Keller explained that using different spacings such as 1, 2, and 5 millimeters affect the Wc and Pa measurements. Tr. 821:3-13 (Keller direct). He illustrated this point with demonstratives showing that scans would intersect more amounts of embossing as the scan spacing increased. *Id*. Dr. Keller testified that "[e]mbossing has a significant effect on Wc and Pa." Tr. 801:21-22 (Keller direct). That is because "Wc and Pa are effectively looking at the waviness peaks . . . of a surface," and each embossment is like a "crater" in a "field," which will boost Wc. Tr. 806:15-807:9 (Keller direct). Dr. Keller further explained the testing he conducted to assess how embossing affects Wc. He scanned the tissue's outer surface "in an unembossed area," and obtained a Wc of 125.1 microns. Tr. 822:3-12, 823:3-6 (Keller direct). When he scanned in "an embossed area," he obtained a Wc of 214 microns – ***seventy percent higher*** than the Wc value of

the unembossed area and far above the claim limit of 140 microns. Tr. 822:3-25 (Keller direct). This showed that "embossed areas" have a "much higher . . . Wc." Tr. 823:7-10 (Keller direct).

FQ did not rebut any of this evidence establishing that different measurement methodologies yield materially different results. No FQ witness offered a contrary opinion, and FQ adduced no contrary evidence. FQ did not have its experts do any testing to try to challenge Dr. Keller's results. FQ's "surface metrology" expert (Tr. 477:2-5 (Brown direct)), Dr. Brown, did not opine on how embossing affects Wc or observe any testing to assess its effects:

> Q. You were not asked to develop an opinion about how embossing affects the measured properties; correct?
>
> A. Correct.
>
> Q. And you did not offer any such opinion; right?
>
> A. Right.
>
> Q. Now, you did not observe any testing that had the goal of assessing the effects of embossing either; correct?
>
> A. Correct.

Tr. 495:20-496:2 (Brown cross). FQ's "expert in tissues" (Tr. 509:24-510:2 (Runge direct)), Dr. Runge, similarly did not conduct any testing to assess whether embossments affect Wc:

> Q. You bet. You didn't do any testing in this case to evaluate whether embossments affect the surface profile of the tissue?
>
> A. No.

Tr. 620:3-6 (Runge cross).

When FQ's witnesses testified about whether embossing affects Wc measurements, they confirmed that it *does*, consistent with Dr. Keller's conclusions. Dr. Runge, for example, admitted that "large embossing," such as the "large pattern embossment" on the "Member's Mark tissue" (Tr. 455:24-456:7 (Massey cross)), has a "large effect" on "the tissue properties":

> Q. They have a complex set of effect[s] on the final tissue property; right, Professor?

> A. If we're talking about in generalities, you know, again, ***small embossing, small effect; large embossing, large effect***. But ***yes, it will affect the tissue properties***.

Tr. 642:21-642:25 (Runge cross). Mr. Pence, the FQ employee who processed FQ's testing data, confirmed that embossing creates "changes in the elevation on the surface of a tissue," so "[i]f you go over [a] specific spot" with embossing, "the profile is going to be wavier"—i.e., have higher Wc. Tr. 467:16-25 (Pence cross).

3. The Asserted Patents Undisputedly Provide No Guidance On Which Measurement Methodology To Use

The unrebutted evidence adduced at trial confirms that the patents fail to provide any guidance as to how to account for embossments or how far apart to space the scans. Dr. Keller explained that "[t]here's no indication in the patent where to test the outer surface," and neither "the patents" nor "the prosecution histories provide any guidance as to where to perform the scans" or "how to account for embossing." Tr. 821:14-21 (Keller direct). He similarly testified that neither the patents nor the prosecution histories tell a POSA how far apart to space the scans. Tr. 820:23-25, Tr. 821:14-21 (Keller direct). That evidence is unrebutted. No FQ witness purported to identify any intrinsic (or extrinsic) evidence that informs a POSA how to account for embossing or how far apart to place the scan lines. FQ's Dr. Brown admitted that the patents provide no guidance about how to account for embossing. Tr. 482:22-483:3 (Brown direct).

4. The Evidentiary Record Compels A Finding Of Indefiniteness

On this record, JMOL of indefiniteness is warranted because "the existence of multiple methods leading to different results without guidance in the patent or the prosecution history as to which method should be used renders the claim indefinite." *Dow*, 803 F.3d at 634 (ruling claims indefinite as a matter of law after jury returned verdict that claims were not invalid).

The Federal Circuit's analysis in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015), is instructive. In that case, "the parties agree[d]" that the claim term "molecular weight" could refer to any of three possible measurements, each "calculated in a different way." *Id.* at 1341. Similarly here, it is undisputed that Wc can be measured in multiple ways, *e.g.*, by using different spacings between scans). *Supra* 11-12. The *Teva* court noted that each of the available measurements "would typically yield a different result for a given . . . sample." 789 F.3d at 1341. The same is true here. Dr. Keller's unrebutted testing shows that Wc in embossed regions is 70% higher than in unembossed regions, so changing the spacing between scans—and thus changing the amount of embossing that is scanned—materially affects Wc values. *Supra* 12-13. Lastly, the *Teva* court noted that "the specification never defines" which measurement should be used. 789 F.3d at 1344-45. Here, it is undisputed that the specification does not disclose how to account for embossing or what spacing to use between scans. *Supra* 13-14. Consequently, as *in Teva*, the asserted patents are invalid as a matter of law. 789 F.3d. at 1345 (reversing the district court, holding claims indefinite).

Because any attempt to define how to measure Wc to determine whether it falls within the claimed range would hinge on "the unpredictable vagaries of any one person's opinion" on how to account for embossing (*e.g.*, how far apart to place the scan lines), they are indefinite. *Dow*, 803 F.3d at 635. The asserted patents, like those previously held invalid by the Federal Circuit, "fail to explain . . . how to consistently and reproducibly measure" Wc. *Pac. Coast Bldg. Prods., Inc. v. CertainTeed Gypsum, Inc.*, 816 F. App'x 454, 459 (Fed. Cir. 2020); *see also Dow*, 803 F.3d at 635; *Teva*, 789 F.3d at 1341-45.

VI. CONCLUSION

The Court should grant judgment as a matter of law that the asserted claims are invalid for lack of written description and indefiniteness.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
rsmith@morrisnichols.com

Attorneys for Defendants

John G. Day (#5207)
Andrew C. Mayo (#2403)
ASHBY & GEDDES
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19801
(302) 654-1888
jday@ashbygeddes.com
amayo@ashbygeddes.com

OF COUNSEL:

Matthew J. Moore
Maximilian A. Grant
Inge A. Osman
Rebecca L. Rabenstein
David A. Zucker
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004-1304
(202) 637-2200

Charles H. Sanders
David W. Rowe
Paul Weinand
LATHAM & WATKINS LLP
200 Clarendon Street
Boston, MA 02116
(617) 948-6000

Dale Chang
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
(312) 876-7700

Jeffrey G. Homrig
LATHAM & WATKINS LLP
140 Scott Drive
Menlo Park, CA 94025
(650) 328-4600

June 21, 2022

CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 21, 2022, upon the following in the manner indicated:

Joseph B. Warden, Esquire — *VIA ELECTRONIC MAIL*
Warren Keith Mabey, Jr., Esquire
Nitika Gupta Fiorella, Esquire
Kelly A. Del Dotto, Esquire
Casey M. Kraning, Esquire
FISH & RICHARDSON P.C.
222 Delaware Avenue, 17th Floor
Wilmington, DE 19801
Attorneys for Plaintiff

Edmond R. Bannon, Esquire — *VIA ELECTRONIC MAIL*
Jeffrey C. Mok, Esquire
FISH & RICHARDSON P.C.
7 Times Square, 20th Floor
New York, NY 10036
Attorneys for Plaintiff

Ethan J. Rubin, Esquire — *VIA ELECTRONIC MAIL*
FISH & RICHARDSON P.C.
One Marina Park Drive
Boston, MA 02210-1878
Attorneys for Plaintiff

/s/ Rodger D. Smith II

Rodger D. Smith II (#3778)